ACCOMPANYING LABELING: Promotional form letter entitled "Dear Doctor" and leaflet entitled "Are opiates now outmoded in pediatric diarrhea?"

LIBELED: 8–1–61, N. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article "acts almost exclusively to inhibit gastrointestinal motor function and does not interfere with gastric secretion, digestive processes, or produce other undesirable atropine like effects when given in the recommended dosage" and that the "only side effect noted was a mild, more or less transient flushing of the skin"; will successfully treat diarrhea, which threatens pediatric patients, without side effects; and stop diarrhea rapidly, without side effects; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and it was not exempt from the requirement since the promotional material for the new drugs was not the same as, or substantially the same as, the labeling authorized by the effective new drug applications; and 505(a)—the effective new drug application did not apply to the conditions for which the articles were promoted to the medical profession, namely, for the treatment of complications of severe pediatric diarrhea-dehydration, electrolyte imbalance, weight loss, pale, ashen skin, sunken fontanel, distended abdomen, and constant crying; nonspecific digestive upsets and for nausea and vomiting.

DISPOSITION: 10–18–61. Default—destruction.

DRUG FOR VETERINARY USE

6862. Zoamix medicated feed premix. (F.D.C. No. 46851. S. Nos. 6–468 T, 7–342 T.)

QUANTITY: 63 50-lb. bags at Augusta, Maine.

SHIPPED: 10–25–61 and 11–28–61, from Newark, N.J.

LABEL IN PART: "ZOAMIX A Premix Medicated * * * For Chickens Only. Active Ingredients: Zoalene (3.5-Dinitro-O-Toluamide) 25%."

RESULTS OF INVESTIGATION: The manufacturer of the article had filed a new drug application which was effective with respect to shipments of the article made to feed manufacturers who had filed effective supplemental new drug applications covering the use of the article in finished feeds. Investigation revealed that the article had been purchased by a dealer at Augusta, Maine for use in the feeds which he manufactured but that such dealer had not filed a supplemental new drug application which was effective for such use.

LIBELED: 12–13–61, Dist. Maine.

CHARGE: 505(a)—the article was a new drug, and an application filed pursuant to law was not effective with respect to the article.

DISPOSITION: 1–3–62. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6863. Various prescription drugs. (F.D.C. No. 46109. S. Nos. 50–529/33 R, 50–535/8 R.)

QUANTITY: 6,431 tablets and capsules and 70 clips of vials, btls., and packs, at Denver, Colo., in possession of Earl Meyer Drug Co.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Physician's Professional Package," "Physician's Trial Package," "Physician's Sample," "Professional Sample," "Sample–Not To Be Sold," and "Professional Specimen."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked by the dealer into containers having labels bearing brand names indicative of manufacture outside the State of Colorado, and quantities of nonrepacked physicians' samples of prescription drugs.

LIBELED: 7–27–61, Dist. Colo.; amended libel 8–25–61.

CHARGE: 502(a)—while held for sale, the statements "Physician's Trial Package," "Physician's Sample," "Professional Sample," "Sample–Not To Be Sold," "Professional Specimen" and similar wording on the labels of a number of the articles of drug were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not then intended for use as "complimentary–not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)—the repacked articles of drug failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(f)(1)—the labeling of the repacked articles of drug failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as required by regulations; and 503(b)(4)—the repacked articles of drug were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–6–61. Default—destruction.

6864. Elixir phenobarbital. (F.D.C. No. 46471. S. Nos. 45–523/4 R.)

QUANTITY: 100 cases, 4 1-gal. btls. each, at Atlanta, Ga.

SHIPPED: Between 2–8–61 and 4–3–61, from Greenville, S.C., by Cambridge Pharmaceuticals.

LABEL IN PART: (Some btls.) "Elixir Phenobarbital Hyoscyamine and Hyoscine Hydrobromide and Atropine * * * Each 5 cc contains: Hyoscyamine Hydrobromide 0.1037 mg. Hyoscine Hydrobromide 0.0065 mg. Atropine Sulfate 0.0194 mg. Phenobarbital 16 mg. Alcohol 20% Mfg. for Grady Hospital, Atlanta, Georgia Mfg. by Cambridge Pharmaceuticals, 117 Cleveland Street, Greenville, S.C." and (some btls.) "Elixir Phenobarbital and Belladonna Alkaloids (NF) Each 5 cc contains: 16.2 mg. Phenobarbital (Warning: May be habit forming) 0.1037 mg. Hyoscyamine Sulfate 0.0194 mg. Atropine Sulfate 0.0865 mg. Hyoscine Hydrobromide 20% Alcohol Caution: * * * Mfg. for Grady Memorial Hospital * * * Atlanta, Georgia Mfg. by Cambridge Pharmaceuticals, 117 Cleveland Street Greenville, S.C."

RESULTS OF INVESTIGATION: Analysis showed that all bottles of the article contained less than 10 percent of the labeled amount of the belladonna alkaloids (calculated as atropine sulfate). The label of some bottles bore the notation NF, however, this article was not a drug the name of which was recognized in the National Formulary.

LIBELED: 10–2–61, N. Dist. Ga.